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ABSTRACT

The purpose of this pamphlet is to clarify the issues pertaining to ownership of research data. It examines legal issues on data management for colleges and universities and suggests ways to better articulate statements regarding data management and ownership. It urges universities, research sponsors, and other pertinent groups to develop policies on data management as they relate to specific disciplines. It reviews definitions of "research data" and "research to be retained" in relation to of policies used by various professional organizations. Data retention issues of custody and length of time to retain data are covered. A poll of 41 universities in the summer of 1993, is reported in which the consensus was that the principal investigator or scientific director should be the custodian of all original data, but opinion varied widely on how long data should be retained. Data ownership is addressed by looking at the legal, university, and government perspectives; as well as that of private sponsors. The slow development by universities of policies regarding data ownership is noted. Also addressed are the conditions for transfer of data and the need for it to be included in future policies. Ten key elements that should be addressed in a policy statement on ownership and retention of research data are identified. A list of 30 acronyms is provided. (Contains reference footnotes.) (LEE)

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Ownership and Retention of Data

ANN R. STEVENS

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Ownership and Retention of Data

Introduction

The topic of ownership[1] of research data generated at universities and other academic institutions[2] and the attendant questions of what and how long data should be retained, who should retain the data, and when and under what circumstances data should be removed from the university are all issues that have long been ignored by both sponsors of research and university administrators. Due largely to these omissions, as well as the lack of well-articulated policies, when asked, "Who owns your research data?" most academicians respond, "I do." The underlying premise is that the ideas leading to the research originated with the faculty[3] and are proprietary to the "creator," regardless of whether university resources or external funds were used in obtaining the results. Moreover, faculty contend that they are responsible for providing the data for replication and validation of their published results by peers, so who better to be the custodian than the person who originally obtained the data.

Faculty ownership of research data might have remained uncontested had the issue of scientific misconduct not appeared with such ferocity in the last decade. Even though there has been intensive scrutiny of research data in several well-publicized cases of misconduct allegations, universities and sponsors (including the Federal government) have been slow to address the contentious issue of data ownership. This is not to imply that these groups do not want to ensure the public's trust of academic research and take positive steps to prevent deviant behavior in the conduct of that research; rather the subject of data management is so complex and controversial that it

1. Ownership is used in the generic to mean all aspects of data management, including ownership, retention and access.

2. Universities and other academic institutions hereafter will be referred to as "universities."

3. Faculty refers collectively to faculty, students, instructors, including post-doctorals, visiting scientists and any other person at a university who is involved in the design, conduct or reporting of research data.

doesn't readily adapt itself to a uniform policy statement.

It is not only misconduct cases that are forcing the issue of who owns and controls research data: the reliance of universities on industry support to supplement Federal sponsorship of research also carries with it certain obligations. For example, industries frequently want to own, or at least have unlimited access to, intellectual property data obtained from research that they sponsor. While industry recognizes the need for universities to own intellectual property rights, a corporate sponsor might be reluctant to invest in a university-owned invention that lacks well-documented supporting data needed to protect proprietary interests.

Research data also have an impact on National initiatives. Although in the 1960's and 1970's, data from applied research were those considered to have economic importance, more recently, results from basic research, especially data obtained with public funds, have become significant in establishing policies for societal benefit. For example, data from basic research may lead to the development of pharmaceuticals and may be needed for the regulatory approval and marketing of drugs. Thus, it is incumbent on universities, their faculties and administrators, to work together in promulgating statements on ownership and control of research data.

The purpose of this pamphlet is to clarify the issues pertaining to ownership of research data, and to assist universities and sponsors, as well as other pertinent groups, to better articulate statements regarding data management. Although the emphasis is on data management in biomedical research, only the subject matter and the research methods are unique. All faculty engage in research: "they collect, interpret, and publish data; and they train graduate students."[4] It would be erroneous, therefore, for universities to promulgate statements on data management only for biomedical or other

4. Steneck, Nicholas H. "Fostering Responsible Conduct in Science and Engineering Research: Current Policies and Actions." *Responsible Science: Ensuring the Integrity of the Research Process*, Volume II. National Academy Press, pp. 3-25, 1993.

scientific research. The issue spans research conducted in all academic disciplines. As such, universities should consider developing general policies on data management, addressing the concerns of particular disciplines with separate policies where necessary. Although not all universities may decide to create such policy statements, the decision should be made through careful analysis rather than by default.

RESEARCH DATA

Definitions

There is little, if any, consensus on the definition of research data. For example, in the first volume of *Responsible Science: Ensuring the Integrity of the Research Process*,[5] "research data include detailed experimental protocols, primary data from laboratory instruments, and the procedures applied to reduce and analyze primary data." In the same proceedings, it was stated that "The term 'research data' applies to many different forms of scientific information, including raw numbers and field notes, machine tapes and notebooks, edited and categorized observations, interpretations and analyzes, derived reagents and vectors, and tables, charts, slides and photographs."[6]

In a report of a workshop on *Data Management in Biomedical Research*,[7] "the participants' definition was broad enough to indicate the whole universe in biomedical and behavioral research data which is subject to ownership, retention and sharing." Alternatively, what constitutes data in the social sciences "is only limited by the imagination of the researchers."[8]

From the perspective of Federal agencies, 45 CFR[9] Subpart 27.401 of the Federal Acquisitions Regulations (FAR) defines data as:

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5. "Scientific Principles and Research Practices." *Responsible Science: Ensuring the Integrity of the Research Process*, Volume I. National Academy Press, pp. 36-66, 1993.

6. *Ibid.* p. 47.

7. Rhoades, Lawrence J. "Workshop Summary." *Data Management in Biomedical Research: Report of a Workshop*, pp. 2-9, 1990. (Sponsored by the Department of Health and Human Services, U.S. Public Health Service, Office of the Assistant Secretary for Health, Office of Health Planning and Evaluation and Office of Scientific Integrity Review).

8. Cordray, David S., Pion, Georgine M., and Boruch, Robert F. "Sharing Research Data: With Whom, When, and How Much?" pp. 39-78, 1990. *Ibid.*

9. Acronyms are listed on page 24.

> recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing or management information.

A definition similar to that provided in the FAR is given in the General Terms and Conditions for the Federal Demonstration Project (FDP) (Section 35, "Rights in Data," Revised, September, 1993), in which nine Federal agencies participated (DOD, NSF, AFOSR, DOE, EPA, NASA, NIH, ONR, and USDA).

Data to be Retained

For purposes of this pamphlet, it is not necessary to have a consensus on a definition of research data because the definition will vary, depending upon the discipline. Instead it is important to identify those data – primary, compiled or derived[10] – that are essential for the researcher[11] to retain and to make available to other scientists, sponsors and/or persons investigating an allegation of misconduct.

The issue of data management, including data retention, is most commonly addressed either through guidelines/recommendations for the responsible conduct of research or through institutional policy. Institutions such as Johns Hopkins University,[12] the Massachusetts Institute of Technology[13] Harvard Medical School,[14] University of Michigan Medical School,[15] and Emory University,[16] among others, have issued guidelines stating that original or primary data should be kept. For example, Emory's *Guide-*

10. Weinberg, Robert A. "Reflections on the Current State of Data and Reagent Exchange Among Biomedical Researchers." *Responsible Science: Ensuring the Integrity of the Research Process*, Volume II. National Academy Press, pp. 66-78, 1993.

11. *Researcher:* Although in this section the researcher is cited to be the gatekeeper of the data, a fuller discussion about who should be responsible for data retention is given in Section IV. A.

12. Johns Hopkins School of Medicine. *Rules and Guidelines for Responsible Conduct of Research.*

13. Massachusetts Institute of Technology. *Report of the Committee on Academic Responsibility.*

14. Harvard University Faculty of Medicine. *Guidelines for Investigators in Scientific Research.*

15. University of Michigan Medical School. *Guidelines for the Responsible Conduct of Research.*

16. Emory University. *Guidelines for the Responsible Conduct of Scholarship and Research.*

lines for Responsible Conduct of Research and Scholarship stipulate that "Where feasible, all original primary data are to be retained by the faculty member or by his/her designate."

Other institutions, including Duke University,[17] the University of Houston,[18] and the Dana-Farber Cancer Institute[19] have developed policies on data management, stipulating that the primary, original data should be retained.

In addition, various professional organizations, including the American Federation for Clinical Research (AFCR)[20] and the American Association of Medical Schools (AAMC),[21] as well as several professional journals (such as the *American Journal of Public Health* and the journals of the American Psychological Association) dictate that primary and original data should be retained in the event that they need to be made available for inspection. AAMC, in fact, includes in its list of "topics on which standards of behavior ought to be developed, ... recording and maintaining primary research data and materials."[22] For Federal grantees, reference to record retention is found in Attachment C of OMB Circular A-110 (Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations). The Section on "Retention and Custodial Requirements for Records" states that: "Financial records, supporting documents, statistical records, and all other records pertinent to an agreement shall be retained, etc."

Although universities have long considered this Section to apply only to retention of financial records (e.g., in case of an audit), as early as 1990, the Public Health Services (PHS) alluded

17. Duke University. *Policy on Data Retention and Access.*

18. The University of Houston. *Interim Policy on Access to and Retention of Research Data.*

19. Dana-Farber Cancer Institute. *Policy for Recording and Preserving Scientific Data.*

20. American Federation for Clinical Research. "AFCR Guidelines for the Responsible Conduct of Research." *Clinical Research*, Volume 37, pp. 510-511, 1992.

21. Association of American Medical Colleges. *Beyond the Framework: Institutional Considerations in Managing Allegations of Misconduct in Research*, 1992.

22. *Ibid.*

to it as being applicable to retention requirements for research data.[23]

More recently, the Assistant General Counsel at the National Science Foundation (NSF) contacted OMB and requested clarification about what is included under the specific provision, "all other records pertinent to an agreement," in the Section on retention requirements in Circular A-110. OMB responded that primary data and laboratory notebooks are considered "other records" that grantees must maintain.[24] The OMB directive for retention of primary data by grantees is also required by the National Institutes of Health (NIH) for its intramural scientists, and is referenced in that agency's *Guidelines for the Responsible Conduct in the Intramural Research Program.*[25]

In summary, original, raw data are obtained, recorded and analyzed in a variety of ways, and can range from results entered in the traditional laboratory notebook to novel approaches designed to develop unique research resources, if not the novel reagents themselves. Universities seeking to define what raw data to retain can refer to the definition provided under the Good Laboratory Practices Standards of the Environmental Protection Agency (EPA) (40 CFR Part 742) and Federal Drug Administration (FDA) (21 CFR Part 58).

> Raw data means any laboratory worksheets, records, memoranda, notes or exact copies thereof, that are the result(s) of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. Raw data include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations and recorded data from automated instruments.

Interestingly, neither the EPA nor FDA include unique specimens in their definitions, but both agencies do require retention of specimens developed in the course of a project.

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23. Rhoades, Lawrence J., "Workshop Summary." *Op. Cit.*

24. April 11, 1994 Letter to Mr. John Chester, Assistant General Counsel, National Science Foundation, from Mr. Harold Steinberg, Deputy Controller, Executive Office of the President, Office of Management and Budget.

25. National Institutes of Health. *Guidelines for the Conduct of Research at the National Institutes of Health*, 1990.

DATA RETENTION

Custody

When discussing who should be the custodian of primary research data, the most frequently cited sources are: head of the laboratory, e.g., the investigator or scientific director responsible for the overall conduct of the research; the department in which the investigator or director holds his academic appointment; or the institution where the research is performed. Although some disciplines advocate retention of research data in archives or depositories (e.g., the Interuniversity Consortium for Political and Social Research, the National Opinion Center, etc.), few scientific researchers are proponents of data retention in national databases or in facilities external to the site where the data were generated. An exception to this statement would be data from large scale clinical trials or epidemiological studies that cannot be easily replicated[26].

Although there could be occasions when either the department or the institution might need to become the custodian of data (e.g., when a faculty member leaves the primary data upon departure from the university, retires or dies), the consensus of faculty, departmental and university administrators, journal editors and professional organizations is that the principal investigator or scientific director should be the gatekeeper of all original data produced in his or her laboratory. Exceptions to this statement are discussed in Section VI, which addresses when and under what circumstances universities should allow original data to be removed from the institution.

In a poll of 41 universities in the summer of 1993,[27] the institutions that responded and provided their guidelines on data management all indicated that the head of the laboratory or unit in which the data were obtained is responsible for data storage. For example, Harvard Medical School's *Faculty Policies on Integrity in*

26. Rhoades, Lawrence J. "Workshop Summary." *Op. Cit.*

27. Stevens, Ann R. Letter sent to 41 research institutions asking for their guidelines/policies on ownership/retention/transfer of research data, Summer 1993.

Science, state that "Custody of all original primary laboratory data must be retained by the unit in which they are generated." Johns Hopkins School of Medicine,[28] University of Michigan Medical School,[29] Dana-Farber Cancer Institute,[30] Duke University,[31] the University of Houston,[32] and Emory University,[33] all have similar statements.

And these statements are by no means limited to universities: the AFCR and the AAMC, for example, have also outlined their views as to who should be responsible for data storage. The former states that "proper retention of data is essential as a means of assuring scientific quality and accuracy and as a safeguard against mistaking error for misconduct. Original experimental data should always be available for reference in the laboratory. Institutions or, ideally, PI's have a responsibility to retain the primary data indefinitely."[34] Similarly, AAMC advises institutions to make clear that "the director of a laboratory must have clearly defined responsibilities for...recording, retaining and storing research or scholarly data."[35] The American Hospital Association (AHA), the American Psychological Association (APA), the American Society for Microbiology (ASM), and the Society of Neuroscience (SN) also assign responsibility to the principal investigator for data retention.

Although most journals remain silent on the issue of data management, the AJPH,[36] the JAMA,[37] and the 20 journals of the APA[38] state in their guidelines for authors that raw data/summary tables, etc., may be required from

28. See fn #12.

29. See fn #15.

30. See fn #19.

31. See fn #17.

32. See fn #18.

33. See fn #16.

34. See fn #20.

35. Association of American Medical Colleges. *Framework for Institutional Policies and Procedures to Deal with Misconduct in Research*. 1989.

36. "Information for Authors." *American Journal of Public Health*. Volume 80, pp. 91-94, 1990.

37. "New Requirements for Authors: Signed Statements of Authorship Responsibility and Financial Disclosure." *Journal of the American Medical Association*. Volume 262, pp. 2003-2004, 1989.

38. American Psychological Association. "Ethical Principles of Psychologists." *American Psychologist*. Volume 45, pp. 390-395, 1990.

authors, and therefore, original data should be retained in the event they need to be available for inspection. The "Uniform Requirements for Manuscripts Submitted to Biomedical Journals," to which hundreds of journals subscribe, do not make data retention a requirement for publication, but authors are advised that "the editor, on accepting a paper, may recommend that additional tables containing important backup data too extensive to publish be deposited with an archival service... or made available by the authors."[39]

With respect to federal government awards, PHS has stated that "The institution is the grantee and assumes legal and financial accountability for the awarded funds (See 52 CFR 50.102 and 52.2 (e)). Therefore, a grantee institution has not only the right, but the obligation, to require a researcher to produce accurate supporting data not only for funded programs but also for grant applications.[40]" Thus, PHS joins institutions, faculty, professional organizations and journal editors in assigning accountability for data storage to the principal investigator of the research.

Length of Time to Retain Data

Researchers' opinions vary widely on the length of time that original data should be retained. Participants in the workshop on Data Management in Biomedical Research were of the general opinion that "data should be kept for a substantial period of time following completion and publication of a study because data are usually requested long after the completion of research, publication, and the close of the grant period."[41] Just as generic was the investigators' preferences for retaining data: "from six to twelve months after a publication appears to indefinitely."[42]

Universities also seem to vary in their policies toward data retention. Some such as

39. "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." *The New England Journal of Medicine*. Volume 324, pp. 424-428, 1991.

40. Office of Research Integrity Newsletter. "Who Owns Research Data and How Long Must it Be Kept?" Volume 2, Number 4, p. 2, 1994.

41. Rhoades, Lawrence J. "Workshop Summary." *Op. Cit.*

42. *Ibid.*

Johns Hopkins University,[43] Duke University,[44] and the University of Michigan Medical School[45] require storage for as few as five years past publication. Others such as the Harvard University Medical School, stipulate that data should be retained "as long as there is any reasonable need to refer to them."[46] Harvard, however, then leaves it to the discretion of the head of the research unit to proscribe a definitive time for storage, if it is other than for "the life of the unit." Additionally, Harvard's guidelines distinguish between the time required for data to be stored for clinical trials and the time required for results obtained from scientific research. For clinical data, the "principal investigator should retain original data for as long as practically possible, but never for less than five years from the first major publication or from the completion of an unpublished study."[47]

At Emory University, the *Guidelines for Responsible Conduct of Research and Scholarship* recommend that data be stored for at least seven years after they are obtained, based on the premise that the half-life for citations to publications is seven years. The seven-year retention period is also the minimal time required by the Geisinger Clinic for data storage, although this institution qualifies the seven-year period to extend to the life of the research unit when deemed necessary.[48]

The retention period for preservation of data produced under federal grants is three years from the date of submission of the last expenditure report (Attachment C, OMB Circular A-110; 45 CFR, Part 74 Subpart D). An exception to the three-year rule would be if there is any pending litigation, claim or audit. In such cases, "the records must be retained until completion of the action and resolution of all issues involved." As previously mentioned, this provision in A-110, while considered in earlier years to be applicable

43. See fn #12.

44. See fn #17.

45. See fn #15.

46. Harvard University Faculty of Medicine. *Faculty Policies on Integrity in Science.*

47. *Ibid.*

48 Geisinger Clinic. *The Maintenance of High Ethical Standards in the Conduct of Research.*

only to financial data, is now also being cited by federal agencies for retention of primary data and laboratory notebooks produced under a federal award. All federal agencies have implementing regulations for A-110; the three-year retention period, therefore, and any extensions thereof, apply to all government grants, with the exception perhaps of FDA regulations. If an FDA-funded study does not fall under the Good Laboratory Practice Standards (GLPS), the FDA requires the investigator to maintain records "for a period of two years following the date a marketing application is approved for the drug; or, if no application is approved for the drug, until two years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified (21 CFR 312.57 (b))."

If the FDA requirements do fall under the GLPS for storage and retrieval of documentation records, raw data, and specimens pertaining to non-clinical laboratory studies, they must be retained in the archive(s) for two to five years. The latter period is required when results of a study are submitted to the FDA in support of an application for a research or marketing permit. If no application is made to the FDA, the records must be retained for only two years from the date the study was "completed, terminated, or discontinued."

Only a handful of professional journals and societies have formally stipulated or published the period of time for which research data should be kept. The AJPH[49] expects its authors "to retain protocols, data, and data analyses, including data tapes, for a period of at least three years after publication of a manuscript, and they (the authors) may be asked to supply their instruments or protocols to others who wish to have that information in order to duplicate the findings."[50] All 20 journals of the APA including the *Behavioral Neuroscience Journal* (BNJ) and the *Journal of Personality and Social Psychology* (JPSP), "are expected to have available their raw data throughout the editorial

49. "Information for Authors." *American Journal of Public Health*, Volume 80, pp. 91-94, 1990.

50. *Ibid.*

review process and for at least five years after date of publication."[51]

Although there may be other journals that refer to data retention and/or storage in their instructions to authors, a review of over 30 journals by this Author did not reveal any others that prescribed a period of time for data retention. Cordray et. al. (fn), made a similar observation when they conducted a review of various journals to determine which, if any had explicit policies for sharing research data, either with other researchers or with person(s) involved in the review of manuscripts.[52]

In addition to the APA, only a few other professional societies have articulated statements regarding retention periods for research data. As mentioned above, the APA[53] specifically states to its members that data must be kept for a minimum of five years. The AFCR, in its "Guidelines for the Responsible Conduct of Research,"[54] suggests retaining data for an indefinite period, whereas the Society for Neuroscience echoes Harvard's recommendation of maintaining data "for as long as there is a reasonable need to refer to them."[55] APS makes a similar statement in its *Guidelines for Professional Conduct.*[56]

As concluded by the participants in the workshop on Data Management in Biomedical Research, journal editors and professional societies need to articulate to authors and members, respectively, their expectation for data management, including retention of and access to research data.

As noted in the Introduction to this Section, opinions vary as to the length of time primary data should be retained. With the exception of patent data, primary data should be kept for a minimum of five years after the results have been published, longer if there is an ongoing investigation or evaluation of the results. The retention period for patent data should extend

51. See fn #39.

52. Cordray, David S., Pion, Georgine M., and Boruch, Robert F. "Sharing Research Data: With Whom, When, and How Much?" *Op. Cit.*

53. See fn #39.

54. See fn #20.

55. Society for Neuroscience. *Policy on Misconduct.* 1989.

56. American Physical Society. *Guidelines for Professional Conduct.* 1991.

at least through the life of the patent, and probably even longer, to protect against interference or infringement of the intellectual property.

DATA OWNERSHIP

Legal Perspective

One of the most contentious issues relating to data management is who owns the data – the university or the researcher? As mentioned in the Introduction, most faculty members consider themselves to be the owner of their research results. However, in her article, "Ownership of Research Data,"[57] Estelle Fishbein makes a compelling argument why, legally, the institution is the owner of research data. Ms. Fishbein states that the basic principle regarding ownership of data by the university is not open to debate, although she does recognize that there are "ethical problems" concerning data ownership generally. She further points out that if academics assert that they own the fruits of their labor, "then they must claim that the work was not done in the course of their employment. And, as a consequence of that position, they must relinquish any right to call on the university or institutional employer for indemnification, insurance, and a legal defense should their research activities give rise to a dispute with governmental authorities or litigation."[58] Ms. Fishbein further points out that, regardless of federal regulations of government-sponsored research, the institution's right to own data "is a natural consequence of the conventional relationship between employer and employee, as it has developed under what is referred to in the law as a 'common law agency doctrine;' that is, the body of law developed by the courts on a case-by-case basis."[59]

University Perspective

Regardless of the legal right to claim ownership of research data (with the exception of statements about ownership of intellectual

57. Fishbein, Estelle A. "Ownership of Research Data." *Academic Medicine*, Volume 66, pp. 129-133, 1991.

58. *Ibid.*

59. *Ibid.*

property), most universities have remained remarkably silent on the subject. No specific mention of who owns the primary data is made, for example, in the guidelines on ethical conduct of research by Harvard Medical School, Massachusetts Institute of Technology, University of Michigan Medical School, Emory University and, more recently, in the policies of Duke University and the University of Houston.

The University of Houston's *Interim Policy on Access to and Retention of Research Data*, in fact states that the University "recognizes that the generators of data (faculty, staff, and students) often believe that they own the data produced in their laboratories, and that they have an interest in ensuring that the data are used in an appropriate manner. At the same time, the University recognizes that it has legal responsibilities with regard to access to and retention of data, particularly data generated under sponsored agreements." Thus, the issue of who actually owns the data is not ever specified.

In a review of other university statements on data ownership, several claimed ownership to the research results. The Brain Tumor Research Center at the University of California, San Francisco states, "methodology and experimental notebooks and related data and records are the property of the University of California."[60] Although Johns Hopkins University allows primary data to be removed from the site, when granting permission to do so, the department director must remind the researchers that, legally, the data are still the property of the University. The Dana-Farber Cancer Institute makes one of the most forceful statements on ownership – "Equally uncontestable is the Institute's ownership and stewardship of the scientific record."[61]

The reluctance of universities to articulate statements about their right to own data is understandable since they are often hesitant to confront those faculty members who are usually very adamant about owning their research

60. Brain Tumor Research Center, Department of Neurobiological Surgery, School of Medicine, University of California, San Francisco. *Guidelines on Research Data and Management.*

61. See fn #19.

results. Indeed, faculty who attended several conferences and workshops in recent years on the topic of data management, including who owns the results of research, were very vocal in their objections to academic ownership. Some researchers argued that "the data historically belonged to the investigator," and that "any change would constitute an unwarranted and unnecessary intrusion into the laboratory."[62] Other researchers expressed surprise that universities might wrest control of their data from them, and one researcher even stated that the university would have to build a facility to hold all of her data now housed in her attic. Concern was also expressed about what happens when a faculty member leaves a University, and needs to take the original data to continue his other research.

Despite those faculty concerns, there is a recognized legal basis for the institution to exercise ownership of research work products. Faculty who object to university ownership of data, however, should keep in mind that 1) not all data have to be retained; 2) not all data have to be retained for an indefinite period of time; and 3) if universities claim ownership, arrangements can be made to allow data to be transferred if a faculty member leaves the institution.

Government Perspective

Another reason that universities have been slow to promulgate policies on data management, especially on the issue of ownership, is that until only very recently, the federal government (e.g., Public Health Service), had not been forthcoming in stating who actually owns the research data generated under federal grants. Although university administrators had heard informally from PHS that grantees own the data, PHS had not formally made such a statement in its Grants Policy Manual. In fact, to the contrary, a published report of the Workshop on Data Management and Biomedical Research (1990) states "when PHS awards a research grant, the data developed by the grantee institution are owned by the grantee institution unless

62. Morgan, Dianna. "Battle Heats Up Over Who Owns Research Data." *The Scientist*, pp. 7, 32, May 28, 1990.

there is a specific condition to the contrary inserted in the grant award statement. The legal principle is a matter of PHS practice and policy; there are no regulations which explicitly prescribe it."[63] A comparable statement was issued at the same workshop by the General Counsel's office at the Department of Health and Human Resources (DHHS),[64] thereby precipitating considerable criticism by researchers and university administrators who attended the workshop. This viewpoint was affirmed yet again following the workshop, when the legal advisor to the NIH Office of Scientific Integrity acknowledged that, although it is not formally in writing, the rule requiring PHS grantees to retain the data from their research in fact infers that the grantee institution owns data. The issue was finally resolved in September, 1994, when the PHS issued the following statement: "Research data generated under PHS funding generally is owned by the grantee institution, not the principal investigator or the researcher producing the data."

Whether other federal agencies, such as the NSF, will follow the lead of PHS in addressing the issue of ownership of data generated under federal grants remains to be seen.

The focus of this pamphlet, thus far, has been on the ownership of data generated under Federal grants and, more specifically, PHS grants. In regard to PHS contracts, the terms of the agreement spell out who owns the research results: "absent some unique restriction, if research data are a deliverable under a contract, the Government is deemed to be the owner of the data, having acquired the data under the terms of the contract."[65] In regard to retention and access to contract data, the Federal Acquisition Regulations in Title 48, CFR, cover the government's unlimited rights to data "first produced in performance of the contract (52.227-14 (b))," while striking a balance between the Government's need and the contractor's legitimate property rights (Section

63. Rhoades, Lawrence J. "Workshop Summary." *Op. Cit.*

64. Waldeman, Howard. "Ownership, Access, Retention, and Sharing of Research Data Produced by PHS Grants or Contracts and Cradas." *Op. Cit.*

65. *Ibid.*

27.402 (b)).[66] For example, unless otherwise specified, "the contractor has the right to use, release to others, reproduce, distribute, or publish data first produced or specifically used by the contractor in the performance of the contract...."[67]

It is beyond the scope of this pamphlet to discuss rights in technical data by other federal agencies, such as the DOD. Those who are interested in this aspect of the topic should refer to the Proposed Rule: Defense Federal Acquisition Regulation Supplement; Rights in Technical Data (48 CFR Part 211, 227, and 252) published in the FR, June 20, 1994, pp. 31584-31620.

Universities participating in Cooperative Research and Development Agreements (CRADAS) with PHS and other federal agencies should be particularly cognizant of the section on ownership, access and the sharing of data and results. "The term, subject data, means all recorded information first produced in the performance of the CRADAS and the term, research results, includes all tangible materials other than subject data first produced in the performance of the CRADA." Although each party participating in the CRADA must agree to share all subject data and research results produced in the course of the research, to make results publicly available and to protect proprietary information, the "producing party" has the rights to ownership of all data and results.

Private Sponsors

Many companies that sponsor research, particularly pharmaceutical companies that support clinical trials, are becoming increasingly insistent in their desire to own the data obtained from their sponsorship. During agreement negotiations, these companies frequently state that they should own the research results because they are paying for the study. Unless an institution can produce a written policy statement dictating that it does in fact own the data from its sponsored research, it may have greater difficulty negotiating ownership with the

66. *Ibid.*
67. *Ibid.*

sponsor. Administrators should emphasize the FDA regulations specifying that a study director must retain data records for at least two years following a marketing application to FDA. During the required retention period, the pharmaceutical company can access the data, but the university, by default, "owns" the data. The sponsor, furthermore, can own the case record forms that are completed by the clinician, with copies retained by the site where the trial was conducted, but the university always retains ownership of hospital and medical records of the patients enrolled in the trial.

In summary, universities legally own the data produced by their faculty. Although they may not want to necessarily articulate their rights to ownership, it is now incumbent upon them to at least convey to faculty who hold PHS grants that they, as the grantee, own the data and therefore are accountable for them.

TRANSFER OF DATA

Although universities can and should claim ownership of research data produced by faculty, especially federally-funded research results, this should not in any way imply that the researchers, including faculty, visiting scientists, students and post-doctorals, can not take with them raw data when they leave. Most institutional guidelines for retention of and access to data state that, upon departure, a faculty member may make copies of his or her data. This statement, however, presupposes that all original data are easily duplicated by conventional methods of reproduction, which is not necessarily true. There are some forms of raw data where reproduction might not capture the original results, e.g., photographs of gel matrices, autoradiograms, etc. The conclusions drawn from such data may have been published, but still may be needed by a departing researcher for extension of the research or for other reasons. Conversely, the raw data may not have been published, but may still be needed by the faculty member who is relocating.

These examples illustrate the importance of establishing, in a policy on ownership and retention of data, the conditions under which a

researcher will be allowed to remove original data from the laboratory. The key phrase here is *the conditions under which original data will be allowed to be removed*, because the university does in fact have the legal responsibility to produce the data, be it in cases of research fraud; disagreements between researchers or between collaborating universities; or the need of private research to have results available for legal, business or political reasons. Ms. Fishbein has stated "records should always be within the control of the institution."[68] To accommodate the needs of departing researchers, institutional policy on data management should stipulate that, upon written request, faculty will be allowed to transfer original data that are impractical to copy, or for other legitimate reasons. Administrators should decide in advance what kind of information and how much detail they want concerning the data that is going to be transferred. At the very least, permission from the institution must be in writing. This "transfer agreement" should be signed by the researcher and his or her supervisor (e.g., the department chair or next supervisor); it should include the research project and grant/contract number under which the data were generated if they were produced under sponsorship; it should provide for access to the transferred data by the university for a specified period; and it should state under what conditions the data can be destroyed (e.g., if it is prior to the required retention period, the university should be notified so that it can approve the request).

The latter requirement should also be imposed on researchers who are not leaving the institution, but who nevertheless may wish to destroy data prior to the required period for storage. Regardless of where the data are destroyed – at the home institution or at a subsequent location – the destruction procedure should be in writing and it should be well-documented. At minimum, it should include the reason for destroying the data, what data were destroyed, who granted approval for their destruction, and the way in which the data were

68. Fishbein, Estelle A. "Ownership of Research Data." *Academic Medicine*. Volume 66, pp. 129-133, 1991.

destroyed. Without such documentation, a sponsor who requests access could easily assume that the data never existed.[69] Responsibility for approving the transfer or destruction of data – or the decision to leave it at the institution – could certainly be assigned to the researcher's supervisor.

One example of a "transfer agreement" for relocating primary data by a departing faculty member can be found in Emory University's *Guidelines for Responsible Conduct of Scholarship and Research*. This agreement is to be executed between the faculty member who is relocating and the department chair; or, if the chair is the departing researcher, between (s)he and his/her supervisor. The agreement specifies, among other things, that federally-funded data must be preserved for at least three years following the date that the last expenditure report was submitted for the award (Attachment C: OMB Circular A-110). However as mentioned previously, Emory University recommends a seven-year retention period for all primary data.

The University of Houston's *Interim Policy on Access to and Retention of Research Data*, while not having a tangible document for data removal, states

> When an investigator leaves the institution, (s)he must recognize that the institution must have access to the data. It's neither feasible nor desirable for the original research records to remain at the originating institution, but departing investigators must understand that they have an obligation to hold their data in trust for the institution, and that such data must be returned to the institution if requested for a period of three years after submission of the final report on the research project for which the data were collected, unless a longer retention period is specified by the sponsor.

Duke University's *Policy on Data Retention and Access* doesn't specifically allow for data removal by a relocating researcher; rather it states that, "in the event an investigator leaves the University for any reason, he/she must notify his/her supervisor or the designated custodian of the location of the research records covered by this policy." Similarly, Johns Hopkins University's *Rules and Guidelines for Responsible Conduct of Research* allow for removal of original data upon written request to

69. *Ibid.*

the department director. In addition, the *Guidelines* state that there must be an itemized description of the data and where they will be relocated.

The preceding discussion about data transfer applies to original data that are not easily or accurately reproduced, as well as to data maintained in a traditional laboratory notebook or other such means used for data documentation. But, among the examples given for other types of data that also need to be covered by institutional policy or guidelines, whether original or not, are such unique research as cell lines, biological compounds, reagents, and the like. The departing investigator obviously needs to have these unique materials to continue his research, but should samples of these materials also be left at the home institution?

If the official authorized by the university to approve the transfer of original data ascertains that the scientist has deposited the novel specimen(s) in a nationally recognized registry (e.g., the American Type Culture Collection, GenBank, etc.), there would be no need to require that samples also be left at and preserved in the unit where they were produced. One exception to this might be another person, a co-principal investigator on a grant, for example who would need a supply of the novel substance(s).

If such deposits have not been made, the home department should identify a person who would be responsible for this task and a facility for storing samples of the novel specimen. Prior to leaving, the researcher should provide this individual with a full inventory of the unique research resource(s) and instructions for ensuring optimal methods for preserving them. If it is impractical for another party at the home institution to oversee storage, then the department head should insist that the departing researcher take responsibility for depositing the novel materials in an acceptable registry.

Although universities should allow original records to be removed when reproduction is deemed infeasible, there are some data that should never be permitted to be relocated by the departing researcher. These include the original hospital and medical records of patients

involved in clinical trials, and data that have been used (or may be necessary) for obtaining patents. Investigators can copy what is practical to reproduce, but the university must exert strict proprietorship over patient records in case of malpractice suits or requests for review of the records by regulatory agencies or sponsors of the clinical trials.

Similarly, original patent data may be needed to ensure the rightful ownership of a patent in cases of interference or infringement. It is quite doubtful that a licensee of a university patent would submit to the removal of data by the inventor who has assigned his invention to the university. The only exception for this might be if the patent was assigned to the "new" university at which the departing inventor is relocating.

ELEMENTS OF A UNIVERSITY POLICY ON OWNERSHIP AND RETENTION OF RESEARCH DATA

As a result of the increased attention, in recent years, on the topic of ownership and retention of data (e.g., since NSF began surveying the top research universities as to how they were complying with their obligation to retain and have access to NSF-funded results),[70] it is imperative that universities develop and articulate a policy that specifically states what is expected of researchers with respect to data management and the conduct of research. In fact, institutions should consider promulgating such a statement rather than issuing it as a guideline. Such guidelines were certainly adequate in the past, but the research climate as well as the perspective of the federal government have changed thereby forcing universities to also change. Institutions of higher education now have in hand an explicit statement from PHS delineating the accountability for research data. A basic university policy may only articulate the institution's position on retention of, and access to, publicly-funded research data, or it may be applicable to all research data produced by its researchers. It won't, however, deal exclusively with data management.

70. Stevens, Ann R. Personal Communication. Office of Inspector General, National Science Foundation.

Whichever avenue a university takes, there are several key elements that should be addressed in a policy statement on ownership and retention of research data, including:

1) The purpose of the policy;
2) To whom does the policy apply, e.g., faculty, visiting scientists, post-doctorals, and students;
3) The research to which the policy applies, e.g., sponsored and/or unsponsored research;
4) The person(s) or office responsible for distribution of and compliance with the policy, e.g., department chair, dean, etc., office of sponsored research, etc.;
5) The ownership rights of the university, possibly qualified to emphasize only the university's accountability for federally-funded research data;
6) The university's expectations for accurate and reliable data documentation;
7) Data Retention, including what data should be retained, e.g., primary or raw data; who is responsible for retention; and the length of time for retention;
8) The conditions for data destruction;
9) Provisions for the transfer of data (with the exception of patent data and clinical records) from the University by a departing investigator; for this, universities may want to develop a standard transfer agreement;
10) Sanctions for non-compliance with the policy.

Faculty and administrators should be involved in the development and implementation of this type of policy. Throughout the process, the institution should stress that its intention is to promulgate a policy that complies with federal and other sponsor requirements. As such, it needs to exert its ownership rights to ensure that published data are available in those cases where they may come into question. The university also needs to explain the importance of it being the vehicle to retain primary patent data and clinical records. At the same time, the researcher needs to be assured that he or she will not lose the rights to his or her research results. If the institution approaches the issue by assuring the faculty that both they and it have a moral responsibility to ensure pro-

per record retention and retrieval, especially data generated with public funds, then implementing a formal policy on ownership and retention of data should be acceptable to the faculty.

As Ms. Fishbein concludes in her historic paper, "Ownership of Research Data," "the questions related to control, use, sharing, and preservation of research data will remain unsettled for some time."[71] Her concern, which is shared by this Author, is that if universities disregard the issue and fail to ensure proper accountability for research data, then the government and/or Congress might intervene and dictate what must be done in this area. To avoid this, universities are strongly encouraged to develop individual policies on data management to convince the government that they are in fact being good stewards of public funds in the area of research data.

List of Acronyms

AAMC	American Association of Medical Colleges
AFCR	American Federation for Clinical Research
AFOSR	Air Force Office for Scientific Research
AHA	American Historical Association
AJPH	American Journal of Public Health
APA	American Psychological Association
APS	American Physical Society
ASM	American Society for Microbiology
BNJ	Behavioral Neurosciences Journal
CFR	Code of Federal Register
DOD	Department of Defense
DOE	Department of Education
EPA	Environmental Protection Agency
FAR	Federal Acquisition Regulations
FDA	Food and Drug Administration
FDP	Federal Demonstration Project
FR	Federal Register
GLPS	Good Laboratory Practice Standards
HHS	Health and Human Services
JAMA	Journal of the American Medical Association
JPSP	Journal of Personality and Social Psychology
NASA	National Aeronautic and Space Administration
NIH	National Institutes of Health
NSF	National Science Foundation
OMB	Office of Management and budget
ONR	Office of Naval Research
ORI	Office of Research Integrity
PHS	Public Health Services
SN	Society for Neuroscience
USDA	United States Department of Agriculture

71. Fishbein, Estelle A. "Ownership of Research Data." *Academic Medicine*. Volume 66, pp. 129-133, 1991.

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